

Service and Facility Specific Policies and Compliance Monitoring

TAC 05/25/06 Discussion Template

I. ESSHB 1688 Guidance

- a) The need for a new and regularly updated set of service and facility specific policies that guide certificate of need decisions [Section 3.2.a]

II. Policy Questions Answered in Discussion 03/16/06

A. How should the process of decision-making be conducted?

CON review should be based on:

- 1) A dynamic state health plan which is updated at least bi-annually;
- 2) Detailed criteria and standards, both general and service/facility specific, which are updated at least bi-annually after consultation with a Technical Advisory Committee; and
- 3) Data from data systems designed to address the specific services and facilities covered such as CHARS counterpart, and others.

B. Who should be the CON decision-makers?

The initial steps in the CON analytical process should be:

- 1) Applications analyzed by CON staff;
- 2) Public disclosure of analysis prior to close of public comment;
- 3) Decision by "CON Chief" vs. rules conclusion by staff (which option?);
- 4) Signature by Secretary of Department of Health designee vs. decision by committee, commission, or other group (which option?);
- 5) Available resources (including staff) with technical expertise are needed for review;
- 6) Advisors will include other state agencies;
- 7) Any advise or report should be released accessible by the public~~ly~~, including prior performance reports;
- 8) Staff analysis (at some determined level) should be completed prior to public hearing;
- 9) No ex parte contact from end of public comment period;
- 10) Application process needs to be as simple/streamlined as feasible;
- 11) Data application/request should require only information necessary for decision process;
- 12) The process should not duplicate aspects covered/managed by other programs or systems; and
- 13) Retain current definitions related to service area designation by specific services and facilities, such as the county for home health, while remaining open to future evolving needs.

C. What factors should be considered in making the decision?

In addition to the existing criteria of community need, financial feasibility, structure and process of care, and cost containment, additional factors include:

- 1) Information related to availability of less costly alternatives;
- 2) Information related to availability of alternative services;
- 3) Benchmarking using national criteria for quality, UM, and others;
- 4) Verification of Medicare/Medicaid accessibility to all residents (as form of population accessibility);

Service and Facility Specific Policies and Compliance Monitoring TAC 05/25/06 Discussion Template

- 5) Information related to current charity care provision by applicant, as well as projected charity care provision upon completion of project;
- 6) History of responsiveness/effectiveness of existing providers in surrounding area related to ability and willingness to address need;
- 7) Consideration for special populations;
- 8) Potential impact on selected quality indicators for population to be served;
- 9) Impact on training and education programs;
- 10) Exceptions or variations for rural (carefully considered and constructed);
- 11) Information collected during public comment period;
- 12) Considerations for Impact on public health and current health system infrastructure;
- 13) Service and facility information from licensure, certification, accreditation and other state agencies; and
- 14) Assure level playing field recognizing that place of service, such as free-standing ambulatory versus a part of hospital, allow for difference in oversight or requirements for CON review or licensure when consistency is desired across all similar services or facilities. and
- 15) Compliance with state health plan.

III. Policy Questions Answered in Discussion 04/13/06

D. When are decision-making timeframes and what are the related considerations?

CON decisions should be made with the following factors in mind:

- 1) Maintain mechanism for notifying public of Letter of Intent and receipt of application, which may trigger submission of competing applications;
- 2) Provide Request-for-Proposal invitations for CON proposals based on service needs determined in the State Health Plan;
- 3) Use plan-driven review cycles which specify certain decision dates and review periods, such as 90-day cycles with decision dates on the 15th of each quarter rather than provider-driven receipt-of-application individual cycles;
- 4) Batch competing applications for similar service types and geographic areas into the same concurrent review cycles with additional criteria and standards to address differential factors among competing applications; and
- 5) Use expedited abbreviated cycles for simple-unchallenged applications which comply with the state health plan and have minimal impact on area health services; and
- 6) Application fees should be established that are sufficient to cover the operational cost of CON analytical activities;

E. Where are the venues and methods for decision-making?

CON decisions should be rendered in a public forum using made in a transparent process:

- 1) Use electronic applications, processing and reporting for public transparency, accountability and public input;
- 2) Provide for public input after release of staff analysis using written response and public hearing formats allowing for public interaction between applicant and decision-maker;

Service and Facility Specific Policies and Compliance Monitoring TAC 05/25/06 Discussion Template

- 3) Assure that burden-of-proof is on the applicant to provide documentation of community need and detailed responsiveness to CON criteria and standards;
- 4) Allow for negotiation prior to decision in order to adjust project size, cost and scope to accommodate demonstrated needs;
- 5) Consistency in review and process is critical, timely and with inter-rater reliability, and
- 6) Transparency of data related to volume, application types, appeals/resolutions, denials, compliance, and others is needed.

F. Why are decisions made, including rationale and impact?

CON decisions should be based on state health plan provisions and community responsiveness including the following provisions:

- 1) Planning-based, analytically-oriented, evidence-based health care criteria and standards which are updated at least bi-annually;
- 2) Structured to compensate for market deficiencies and limitations, anticipate changes in market dimensions, and foster efficiency and delivery competitiveness;
- 3) Designed to highlight and accentuate quality;
- 4) Promotes balance considering economic and quality competition within the context of health care market realities;
- 5) At a minimum, decisions should cover limited scope, inpatient, high cost/low volume/high expertise major services and facilities that would impact the public infrastructure, services such as transplant, trauma and others;

G. How are compliance activities conducted?

Conduct post-decision monitoring relative to following factors.

- 1) During the initial pre-operational phase, limit CON to no more than one-year before capital expenditure, and no more than two years to commencement of service, with provisions for CON-approved time extensions for both based on circumstances beyond the control of the applicant;
- 2) Once the proposed service or facility becomes operational, establish the length of compliance accountability and oversight for at least five years;
- 3) Provide for annual reporting of service utilization and costs;
- 4) Cross-check licensing, certification, registration and/or reimbursement sources about scope of services and costs compliance with approved application;
- 5) Establish penalties for non-compliance with provisions of the CON-approved application such as curtailment of services, fines or others;
- 6) Provide for periodic progress reports each six months after decision until the service becomes operational, then require documentation of completed costs;
- 7) Maintain communication between affected state agencies about project development and operational progress;
- 8) Monitoring of a CON-approved individual service or facility shall mean the submission of written documentation describing the steps completed and their related costs to establish the service or facility, plus data reporting the utilization and charges once the proposal becomes operational.

Service and Facility Specific Policies and Compliance Monitoring TAC 05/25/06 Discussion Template

- 9) Charity care should be monitored, reported and followed-up on using direct reporting (such as annual reports), and indirectly reported information (such as toll-free complaint services), with penalties for non-compliance;
- 10) Public funding should be established to support monitoring and compliance activities;
- 11) CON may be defined as a non-exclusive “franchise” for a given service area with a responsibility to monitor the development of an approved service or facility until it is operational, and operation of an approved project for at least five years;
- 12) A process for monitoring ongoing compliance, with ramifications for non-compliance needs to be part of the entire system conducted in cooperation with licensure; and
- 13) Conduct post-decision monitoring for at least five years relative to scope of service, cost compliance and performance reporting.
- 14) Enforcement provisions should be developed with penalties including civil fines, suspensions, probations and CON forfeiture.

H. What data sources are used to monitor health services?

Services requiring CON review should be established and/or enhanced to support application analysis and performance monitoring:

- 1) Provide for the reporting of occupancy and other utilization data for all related long-term care and acute care services, both inpatient and outpatient, in all service settings; recognizing that the shift in setting is to outpatient venues;
- 2) Ongoing data collection should be acquired and reported by an independent state agency using consistent and reliable performance measures;
- 3) Feedback mechanisms should be established to periodically update data to be responsive to the analytical and compliance needs of CON;
- 4) Data should be publicly available for applicants and observers to assure transparency within the monitoring system;
- 5) Ongoing monitoring should be consistent for services and facilities in CON review, as well as existing similar existing services and facilities; all data collection should feed into one system for “old” as well as “new CON approved” services;
- 6) Need comprehensive outpatient data system because the location of service provision (and resultant cost) has shifted to outpatient setting;
- 7) Financial and utilization information related to charity care, quality, and cost should be applicable to not just CON covered services, but should be applied to broader area covered by the state health plan; and
- 8) The data for CON analysis and monitoring should be a subset of a comprehensive data system for state health planning which is a public pathway to improved data collection methodology and reporting consistent with technological advances.